MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

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Abstract

We are developing a new class of implantable electronic devices for a wide range of neural prosthetic applications. Each implant consists of a microminiature capsule that can be injected into any desired location through a 12 gauge hypodermic needle. Multiple implants receive power and digitally-encoded command signals from an RF field established by a single external coil. The first type of implant is a single-channel microstimulator equipped with capacitor-electrodes that store charge electrolytically and release it upon command as current-regulated stimulation pulses. We are also working on implants equipped with bidirectional telemetry that can be used to record sensory feedback or motor command signals and transmit them to the external control system.

In the past quarter, we have continued to refine the fabrication and packaging technology, with particular emphasis on the infrared laser sealing of the glass capsule and hermetic feedthroughs. We completed the design and simulation of two new IC chips for an improved microstimulator and for a test of a power-efficient bidirectional telemetry link. We have prepared a journal article describing results of a novel method to quantify migration of cylindrical implants through muscle.

Administrative

PERSONNEL CHANGES

Primoz Strojnik is no longer with the Mann Foundation. Advanced Bionics Corp. has assigned three full-time staff to work with Joe Schulman and Cecilia Tanacs at the Foundation on this project: David Payne (manufacturing engineer), Abe Smith (research technician), and Irma Vasquez (assembly technician).

COMMUNICATIONS

In order to facilitate communication between the Mann Foundation and Queen's University, an ISDN telephone line and high speed modem have been installed with service to the internet. The Connectix VideoPhone system is in use and remote file access and terminal sessions will soon be available between engineering and documentation computers at both locations.

Work at Mann Foundation

ELECTRONIC SUBASSEMBLY

As shown in accompanying Figure, we have completed an analysis of component dimensions and manufacturing tolerances as a step toward improving manufacturability and establishing test and inspection criteria that can be performed by a technician at various steps. About 40 working electronic subassemblies have been built according to these new procedures. Receiver coils with different wire types and gauges were wound on various devices for evaluation at IIT.

HERMETIC PACKAGING

The carbon dioxide infrared laser was rebuilt to incorporate various process improvements. The optical path was revised to improve the accuracy of beam alignment and focus and the range of defocussing available. A calibrated power control was added, with facility for a microcontroller to produce programmable power ramps. The stepping motors were replaced with gearless units capable of rotating the parts under the laser beam at much higher speeds. New chucks were designed for the feedthroughs and glass tubing to improve mechanical alignment and ease-of-use.

The batch-process for applying glass beads to the Ta stem and Pt-Ir tube was abandoned because of the long cycle time and difficulties controlling the atmosphere in the oven. With the improved laser setup, reproducible hermetic seals can be achieved efficiently by melting the beads on the rotating metal parts one at a time. We have reinstituted the practice of abrasive polishing of the Ta stems to remove longitudinal scratches.

The glass-to-glass seals (capillary tubing to glass bead) can now be produced with acceptable residual stress in the glass (less than 3000 PSI by photoelastic stress analysis). Key improvements included rotating the parts fast enough to distribute the heat evenly, reducing the power gradually after sealing and shaping the beam to encompass exactly the width of the desired seal.

Since we began the development of this technology, there have been changes in the commercial availability of various glasses that are suitable for the package and hermetic seals. Given the amount of preclinical regulatory testing required for human implantation, it is essential that we settle on a material that will be available in the long run. We have mostly worked with borosilicate glass, either as Corning 7800 (no longer available) or Kimbel N51A. Its thermal coefficient of expansion is 5.5 (x10-6/°C), which was a good match to the iridium feedthrough that we used previously (6.0), and adequate match to the tantalum stem (6.5), but a poor match to the Pt-10Ir tube now in use (8.7). We have some previous experience with Kimbel R6 glass, a soda lime glass with a thermal coefficient of 9.3, which would provide a desirable compression seal to both metal feedthroughs. We have ordered complete sets of glass beads and capillary in both N51A and R6 glasses for comparison. R6 is no longer manufactured, so if it is superior, we will need to select, obtain and qualify one of the similar soda-lime glasses now in production.

FINAL SEALS

We have defined an improved sequence for mounting the Ir electrode and closing the hollow Pt-Ir feedthrough that vents the capsule. This subassembly is now made by YAG laser tack-welding of the Ir electrode to the middle of the Pt-Ir tube, leaving an extension past the outside surface of the Ir washer to be used for fixturing. The Pt-Ir washer that provides the contact with the spring is similarly tack-welded to the tube after threading on a glass bead between the two washers. Alternatively, we are looking into tack-welding a tapered spring directly to the tube, eliminating the need for the washer and the separate spring. The glass bead is melted onto the tube by the IR laser and is melted to the glass capillary of the capsule subassembly after the electronic subassembly is loaded inside. The final seal is made by inserting a Pt-Ir wire into the Pt-Ir tube, cutting it flush with the outside surface of the Ir electrode, and melting the end shut. This greatly reduces the amount of energy needed to complete the final seal and reduces thermal stress on the glass seals.

MICROSTIMULATOR CHIP DESIGN

Conversion to the dual-voltage AMI process was somewhat more complex than originally anticipated. Simulations were completed successfully and layout is about 90% complete, with projected release of the design to the foundry in August, along with the transceiver chip described below. Design features include higher stimulus compliance voltage (20V vs. 8V), four recharge currents (0, 10, 100, 500 μA), lower quiescent power draw and more reliable data detection.

A major design review was held in lae March on the microstimulator design, with special attention being focused on the data detection, newer rectification and high voltage (20 volts) circuitry. Major design changes resulted which we subsequently tuned by P-SPICE simulation.

The chip was lengthened to permit a larger on-board power storage capacitor to power the chip circuitry. The new layout in which the chip is sandwiched between the ferrites permitted this and also prevents light contact with the chip. Light falling on the chip interrupts the functionality and was a nuisance problem during testing.

Work at Queen's U.

ANODIZATION & ACTIVATION OF ELECTRODES

We have built and successfully used a 10-station system for semi-automatic anodization of the Ta electrodes and activation of the Ir electrodes, as described in the Appendix. The accompanying Table shows the results of the current leakage tests following anodization of Ta electrodes on 33 dummy capsules equipped with interconnected electrodes but no driving electronics. They are all better than our target of 1 μA, with many at much lower values. We have also successfully used 1 Hz square-wave activation of the iridium and a new deactivation protocol that eliminates the partial activation that often occurs spontaneously on the Ir surface, making it difficult to quantify the net activation achieved. The next step is to build dedicated potentiostatic circuitry to replace the BAS CV-27 equipment that now must be used with the system.

WATER GETTER

After reviewing the various drying agents available, we concluded that anhydrous magnesium sulfate offered the highest capacity in a biocompatible salt, reducing possible adverse effects in case of inadvertent release from the packaging. As shown in the accompanying Figure, we have molded hemicylindrical shapes (1.37 μg) from MDX4-4210 Silastic filled to 70% by weight with anhydrous magnesium sulfate. At full hydration with 8 water molecules per salt molecule, each such getter slug should absorb 0.97 μl liquid water. To test their performance, we made dummy microstimulator capsules in which we placed 0.5 μl water before sealing. Capsules sealed without a getter slug immediately developed a visible condensation layer of water vapor on the inside of the glass that persisted for the 7 days of the test. Capsules with a getter slug never formed a condensation layer and the visible water droplet originally injected into the capsule had disappeared entirely within eight hours.

IN VIVO MIGRATION STUDY

One recurring question regarding use of microstimulator devices within actively contracting muscles is the possibility of migration. During our previous chronic stimulation studies in cats, thresholds were generally stable and microstimulators were found at post mortem in approximately the locations into which they were inserted. In order to study more systematically the potential for these types of devices to migrate through muscle, a novel method based on the stable fluorescent tracer, Procion Yellow, was developed and tested on dummy glass capsules with varying profiles. As described in the Appended manuscript (submitted to J. of Long-Term Affects of Medical Devices), even relatively sharp, smooth capsules without the fixation points afforded by the microstimulator electrodes show virtually no tendency to migrate through muscle in actively behaving animals. It would appear that as long as the implanted material is biocompatible and nontoxic, a stable connective tissue encapsulation forms rapidly and prevents migration of such foreign bodies implanted into muscle. (This work supported by the Canadian Neuroscience Network of Centres of Excellence.)

Work at Illinois Institute of Technology

TRANSCEIVER CHIP DESIGN

In our previous silicon breadboard, we were able to demonstrate the feasibility of using a single coil in the microstimulator both to receive power and data and to act as the tank circuit and antenna for outgoing RF transmission at the same frequency. The next silicon breadboard is a demonstration of the feasibility and achievable modulation rates for incoming and outgoing data transmission based on the suspended carrier mode of operation described previously. This will be done by a chip that records in a shift-register the sequence of detected carrier half-cycles during incoming RF transmission. The chip then telemeters out that information as a sequence of AM-encoded bits after it detects a special carrier sequence consisting of a precharge (6 carrier cycles without a pause) followed by carrier cessation (sleep-mode).

Redesign of the circuitry for compatibility with the AMI foundry processes provided both the need and the opportunity to make further improvements in the power efficiency and sensitivity of the data detection system, which are detailed in the Appendix. This design has passed intensive simulation and is now in layout. Release to the foundry is anticipated in August, with chips likely to be available for evaluation by early October.

Plans for Next Quarter

IMPLANTS

- Select and obtain glass
- Begin preclinical materials testing
- Build functional microstimulators using documented procedures
- Build new μPCB for new IC chips
- Obtain new microstim IC chip and evaluate
- Obtain transceiver test IC chip and evaluate

EXTERNAL DEVICES

- Complete two new cat coil systems from chronic animal testing
- Build eight bedside controller hardware/software systems for beta testing
- Complete, test and begin use of chronic in vitro temperature cycle test system
- Complete documentation for all external hardware and software

List of Appended Material

PROTOCOL FOR ANODIZATION AND ACTIVATION OF μSTIMS

SUBMITTED MANUSCRIPT: A NOVEL METHOD TO IDENTIFY MIGRATION OF SMALL IMPLANTABLE DEVICES

MICROTELEMETRY TEST CHIP, BLOCK DIAGRAM OF REPEATER CHIP